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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,443	12/12/2001	Carlo Farina	P32330	7781

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EXAMINER

HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,443

Applicant(s)

FARINA ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-21 and 26 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for many of the diseases, does not reasonably provide enablement for viral conditions, Alzheimer's disease and solid tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited the treatment of solid tumors and Alzheimer's disease, but the specification is not enabled for the treatment of said diseases.

There has been recited the treatment of viral conditions, but viral conditions are very broad in nature. Viral conditions include: viral hepatitis, sore throat, Encephalitis, Myocarditis, common cold, Enteroviruses, Labyrinthitis, Lymphocytic choriomeningitis (LCM), AIDS, etc.

Viral hepatitis is any type of liver inflammation caused by a viral infection. The three most common viruses now recognized to cause liver disease are hepatitis A, hepatitis

B, and hepatitis C. Several other types have been recognized: hepatitis D, hepatitis E, and the recently identified hepatitis G.

Sore throat, also called pharyngitis, is a painful inflammation of the mucous membranes lining the pharynx. It is a symptom of many conditions, but most often is associated with colds or influenza. Sore throat may be caused by either viral or bacterial infections or environmental conditions.

Encephalitis is an inflammation of the brain, usually caused by a direct viral infection or a hypersensitivity reaction to a virus or foreign protein. Brain inflammation caused by a bacterial infection is sometimes called cerebritis. When both the brain and spinal cord are involved, the disorder is called encephalomyelitis. An inflammation of the brain's covering, or meninges, is called meningitis.

Myocarditis is an inflammatory disease of the heart muscle (myocardium) that can result from a variety of causes. Most cases are produced by a viral infection.

The common cold is a viral infection of the upper respiratory system, including the nose, throat, sinuses, eustachian tubes, trachea, larynx, and bronchial tubes. Although over 200 different viruses can cause a cold, 30-50% are caused by a group known as rhinoviruses.

Enteroviruses are so named because they reproduce initially in the gastrointestinal tract after infection occurs. Despite this, they usually do not lead to intestinal symptoms; rather it is their spread to organs, such as the nervous system, heart, skin, and others that causes disease. Enteroviruses are part of a larger group of viruses known as

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Picornaviruses. The word comes from the combination of "pico" (Spanish, meaning "a little bit"), and RNA (ribonucleic acid, an important component of genetic material).

Labyrinthitis is an inflammation of the inner ear that is often a complication of otitis media. It is caused by the spread of bacterial or viral infections from the head or respiratory tract into the inner ear.

Lymphocytic choriomeningitis (LCM) is a viral infection of the membranes surrounding the brain and spinal cord and of the cerebrospinal fluid.

Acquired immune deficiency syndrome (AIDS) is an infectious disease caused by the human immunodeficiency virus (HIV). It was first recognized in the United States in 1981. AIDS is the advanced form of infection with the HIV virus.

Since the viral conditions are broad in nature, it is not possible to treat viral conditions in general.

The treatment of solid tumors has been claimed. It is not possible to treat tumors generally. Tumor covers cancers and neoplasms that are cancerous or not. A neoplasm is any abnormal tissue that grows by cellular proliferation more rapidly than normal, or continues to grow after the stimulus that initiated the new growth has ceased, or shows lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such a term also covers precancerous conditions such as lumps, lesions, and polyps. In addition, "tumor" covers things other than neoplasms. It also covers any kind of swelling arising from

inflammation. Thus, the claim would cover treatment of many kinds of inflammation. The specification cannot support that.

In claim 21, a method of treating Alzheimer's disease has been recited. The central characteristic of Alzheimer's disease is the deficiency in the level of the neurotransmitter Acetylcholine that plays an important role in memory. Alzheimer's disease can be treated only by Acetylcholinesterase inhibitors that reduce the depletion of acetylcholine. The skill level in the art is so low that the only treatment available to this day is drugs that inhibit Acetylcholinesterase. Thus, a rejection under 35 U.S.C. 112, first paragraph is proper.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited prevention of hypercholesterolemic, but the specification is not enabled for the prevention of hypercholesterolemic. To this

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day, the only treatment possible is to treat the disease, but not preventing someone from having hypercholesterolemic at first place.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term "heterocyclyl" is indefinite. What is the size of the ring? What is the number and nature of the heteroatoms? Can the ring be fused or spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated? Cf *In re Wiggins*, 179 USPQ 421, 423.

b. In claim 1 or elsewhere in the claims, the term "substituted" is indefinite. Substituted by what? What are covered and what are not?

c. Regarding claim 21, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

d. Regarding claim 21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

d. Regarding claim 21, the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

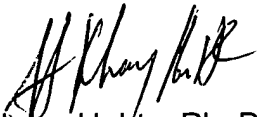
e. In claim 21, a method for the treatment of "transplantation" is not clear. How can one treat transplantation? A "transplantation" is a medical procedure but not a disease.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
February 11, 2003